

(2) Distribute to executive secretaries of initial review and technical evaluation groups, and to PHS contracting offices, lists of institutions that have an approved Assurance;

(3) Advise contracting offices and awardee institutions concerning the implementation of this policy;

(4) Evaluate allegations of non-compliance with this subpart;

(5) Have the authority to review and approve or disapprove waivers of this subpart (see paragraph (d) of this section); and

(6) With other PHS officials, conduct site visits to selected institutions.

(b) *Responsibilities of PHS contracting offices.* PHS contracting offices shall not make an award for an activity involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance of file with OPRR, and the institutional official has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals. If an institution is not listed, the contracting office shall ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

(c) *Conduct of special reviews/site visits.* Each awardee institution is subject to review at any time by PHS staff and advisors, which may include a site visit, to assess the adequacy of the institution's compliance with this policy.

(d) *Waiver.* Institutions may request a waiver of a provision of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided, and the waiver is approved in writing by OPRR.

Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies

PHS 380.301 Scope of subpart.

This subpart provides policies and procedures pertaining to the acquisition

of drug products and medical supplies by PHS or PHS's contractors.

PHS 380.302 Acquisition of drugs.

PHS 380.302-1 Policy.

(a) Drugs shall be acquired at the lowest possible price consistent with acceptable standards of identity, strength, quality, purity, safety and effectiveness, and with due regard for the welfare of the patient and the professional judgment of the prescriber.

(b) Contracting activities shall ensure that drugs are acquired by generic name on a competitive basis whenever it is possible to obtain therapeutically effective drugs of established quality. However, the professional judgment of the prescriber to request drugs by brand name or house designation must be recognized when the best interest of the patient requires it. Similarly, scientific investigators have the prerogative to request drugs having end-product characteristics considered necessary for the conduct of research or investigations.

(c) Prior to taking any acquisition action, the contracting officer shall ensure that the requested drug products are not available from mandatory sources such as Federal Supply Schedules. Part 103-26 of the HHS Material Management Manual describes sources of supply for drugs.

PHS 380.302-2 Solicitation and contract requirements.

The contracting officer should consider including statements similar to the following in solicitations and resultant contracts pertaining to drug products:

(a) The offeror (contractor) guarantees that all requirements established by the Food and Drug Administration, HHS, have been met. These requirements include: plant sanitation, manufacturing, packaging, labeling, identification, strength, quality, purity, safety, and effectiveness.

NOTE: The contracting officer may want to cite the applicable reference(s) pertaining to the FDA requirements.